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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,031	03/02/2004	Kenneth C. Kennedy II	10000/303	1370

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EXAMINER	
PATEL, SHEFALI DILIP	
ART UNIT	**PAPER NUMBER**
3709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/792,031	KENNEDY ET AL.	
	Examiner	Art Unit	
	Shefali D. Patel	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/26/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The inventions are distinct, each from the other because of the following reasons:

1. This application contains claims directed to the following patentably distinct species:

   Species A: Claims 1-25, the distal portion of the stiffening member, of a balloon catheter, being non-fixedly connected to the distal end of the inflatable balloon.

   Species B: Claims 26-32, the distal portion of the inner catheter, of a balloon catheter, being fixedly connected to the distal end of the inflatable balloon.

The species are independent or distinct because these two species are mutually exclusive from each other as evidence from, for example, the illustrations of Figure 8 (species A) and Figure 9 (species B).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. During a telephone conversation with Michael Milz on 7/23/07, a provisional election was made with traverse to prosecute the invention of Species A, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

3. Claims 1, 7-9, and 12 are objected to because of the following informalities:

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the term "shaft" has never been used in the specification and is only used in the claims. For examining purposes, the term "shaft" is assumed to be the outer tube of a catheter.

Appropriate correction is required.

Drawings

4. The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this

Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

If the application is allowed, the applicant will be given a TWO MONTH time period to submit new drawings to replace the informal drawings that have been submitted.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7, 13, 14, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al (EP 1016430).

In regards to claim 1, Sakai et al teaches:

a. an inflatable balloon with a balloon wall defining an interior volume, a distal end, a proximal end, and a central portion (Figure 1A, balloon film [22])

b. a catheter comprising an elongated shaft extending between a distal end portion and a proximal end portion (Figure 1A, outer tube [8]), the proximal end comprising a connector (Figure 1B, connector [40]) configured to engage an inflation device (column 9, lines 14-23), the distal end of the elongated shaft fixedly connected to the proximal end

of the balloon (column 7, lines 36-39), and a lumen (Figure 1A, first lumen [12]) extending through the shaft and in fluid communication with the interior volume of the balloon (column 7, lines 41-43 and 47-49)

c. a stiffening member (Figure 1A and 2, inner tube [10]) extending distally from the distal end portion of the catheter and through the interior volume of the balloon, the stiffening member being non-fixedly connected to the distal end of the balloon (column 7, lines 54-57)

d. movement of the distal end of the balloon relative to the proximal end of the balloon is not restrained by the catheter (Figure 1A)

The distal end of the balloon is not attached to the elongated shaft of the catheter (Figure 1A, outer tube [8]) and so is not restrained relative to the proximal end of the balloon, which is attached to the elongated shaft.

e. axial movement of the distal end of the balloon relative to the proximal end of the balloon in a direction generally parallel to the axis of the shaft is not restrained by the stiffening member (column 7, lines 55-57)

This is because the stiffening member is freely slidable in the axial direction (Figure 1A, inner tube [10] and balloon film [22])

f. transverse movement of the distal end of the balloon relative to the proximal end of the balloon in a direction generally perpendicular to the axis of the shaft is restrained by the stiffening member (column 8, lines 7-10)

i. The stiffening member in contact with the distal end of the catheter and the proximal end of the balloon allows for the restraint of transverse movement at

the proximal end of the balloon (Figure 1A, inner tube [10], outer tube [8], and balloon film [22]), and the stiffening member in contact with the valve element allows for the restraint of transverse movement at the distal end of the balloon (Figure 1A, inner tube [10] and valve element [60]).

ii. The following table shows the structural similarities of the application (10/792,031) and Sakai et al (EP 1016430) for the restraint of transverse movement of the balloon:

10/792,031	EP 1016430
The stiffening member [174] is freely disposed within the lumen [176] of the catheter	The inner tube [10] is freely disposed within the first lumen [12] of the outer tube [8]
The distal end of the catheter [162] is fixedly connected to the proximal end of the balloon [168]	The distal end of the outer tube is fixedly connected to the proximal end of the balloon film [22]
The stiffening member is in contact with the proximal end of the balloon via the distal end of the catheter	The inner tube is in contact with the proximal end of the balloon film via the distal end of the outer tube
The stiffening member is non-fixedly connected to the distal end of the balloon via the sleeve [180] and the end cap [184]	The inner tube is non-fixedly connected to the distal end of the balloon film via the valve element [60]
The stiffening member is slidably disposed in the axial direction with the sleeve	The inner tube is slidably disposed in the axial direction with the valve element

In view of the similarities between the claimed catheter and the catheter taught by EP 1016340, it is reasonable to expect that the limitations in item f of claim 1 are inherently present in the catheter of EP 1016340.

According to MPEP 2112, V, "Where ... the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. **Whether the rejection is based on "inherency" under 35 USC § 102, on prima facie obviousness" under 35 USC § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products."** In re Best, 562 F2d 1252, 1255, 195 USPQ 430, 433-4 (CCPA 1977).

In regards to claim 7, Sakai et al teaches that the stiffening member comprises a proximal portion extending along and generally parallel to the shaft of the catheter (Figure 1B, inner tube [10] parallel to outer tube [8]).

In regards to claim 13, Sakai et al teaches that the distal end of the balloon comprises a sleeve with the distal end of the stiffening member being slidably disposed within the sleeve (Figure 1A, valve element [60] and inner tube [10]; column 9, lines 49-55). In this case, the valve element is performing the same function as a sleeve.

In regards to claim 14, Sakai et al teaches that the sleeve comprises a distal terminus that is spaced away from the distal end of the stiffening member so as to permit axial movement of the distal end of the stiffening member relative to the distal end of the sleeve (Figure 1A, valve element [60] and inner tube [10]).

In regards to claim 19, Sakai et al teaches that the balloon catheter further comprises an inflation device for inflating or deflating said balloon, said inflation device being attached to the connector on the proximal end portion of the catheter (column 9, lines 14-23).

In regards to claim 20, Sakai et al the connector has a male luer fitting and a detachable cap with a female luer fitting (column 9, lines 14-32). It is inherent that the cap would be removed to introduce the inflation device and the inflation device would have a female luer fitting, just like the female luer fitting of the cap, to connect to the male luer fitting of the connector (column 9, lines 30-32). It is trivial which type of luer fitting both the connector and the inflation device has as long as one has a male luer fitting and the other has a female luer fitting.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al, as applied to claim 1 above, in view of Mulder (US 5,700,242).

In regards to claims 2-4, though Sakai et al does not teach of the balloon's axial length being different in the three following states: deflated state, fully inflated state, and partially inflated state, Mulder teaches that the balloon is shortened longitudinally, in the axial direction, when it is inflated (column 2, lines 42-51). Therefore, as the balloon is inflated, the axial length decreases, which means that the deflated axial length, the partially inflated axial length, and the fully inflated axial length would all be different. To a person having ordinary skill in the art, it would be obvious to apply the teachings of Mulder to those of Sakai et al in order to facilitate greater radial expansion of the balloon, without deflecting the tip of the catheter, as the as the axial length of the balloon decreases with inflation of the balloon (column 2, lines 39-44).

In regards to claim 5, Sakai et al teaches that the balloon film is made of softer materials, such as polyurethane, but does not indicate if the balloon wall material is comprised of one of a non-elastic, non-compliant, or semi-rigid material. Mulder teaches that the balloon is made of an inelastic material (column 2, line 28). It would be obvious to apply the balloon material of Mulder to the balloon taught by Sakai et al because Mulder divulges that the use of their material allows for the calculation of the maximum radial diameter that the balloon can inflate to, as further inflation past this maximum radial diameter can cause buckling of the inner catheter shaft, which would deflect the tip of the catheter (column 2, lines 27-37).

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al, as applied to claim 1 above, in view of Weber et al (US 2003/0130716).

In regards to claim 6, though Sakai et al does not teach of the balloon wall comprising axially oriented creases or pleats to facilitate radial compression of the balloon when deflated, Weber et al teaches that it is common practice to form a number of axially oriented wings in the wall of the balloon and fold the wings down along the side of the balloon (page 2, paragraph [0011]; Figure 2, longitudinal wings [6]). It would be obvious to apply the axially oriented creases or pleats taught by Weber et al to the modified device of Sakai et al because Weber et al teaches that such folding of the creases or pleats helps to minimize the diameter of the deflated balloon (page 2, paragraph [0011]).

10. Claims 8-10, 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al, as applied to claim 7 above, in view of Goodin (US 5,425,712).

In regards to claim 8, though Sakai et al teaches that the proximal portion of the stiffening member is disposed within the lumen of the shaft of the catheter (Figure 1B, inner tube [10]), they do not teach that the proximal end of the proximal portion of the stiffening member is fixedly connected to the proximal end of the catheter. Goodin teaches of a stiff inner tube with a proximal end that is securely attached to the proximal end of the catheter via a branched hub (column 3, lines 6-8). It would have been obvious to apply the teachings of Goodin to those of Sakai et al in order to increase the rigidity of the proximal end of the catheter, thereby providing additional support to the proximal end of the catheter.

In regards to claim 9, Sakai et al teaches that the lumen of the shaft of the catheter has a first cross-sectional area and the stiffening member has a second cross-sectional area, with the second cross-sectional area being less than the first cross-sectional area (Figure 1A, first lumen [12] and inner tube [10]) so as to permit an inflation fluid to flow through the lumen between the connector on the proximal end portion of the catheter and the interior volume of the balloon (column 9, lines 14-22).

In regards to claim 10, Sakai et al teaches that the distal end portion of the catheter comprises a distal end that terminates within the interior volume of the balloon (Figure 1A, outer tube [8] and balloon [22]) with the distal end comprising a port to permit inflation fluid to flow between the lumen of the catheter and the interior volume of the balloon (column 9, lines 14-22). The port extends longitudinally along the connector to the distal end of the catheter (column 9, lines 23-24; Figure 1B, port [16], connector [40]).

In regards to claim 12, Sakai et al teaches that the distal end portion of the catheter comprises a distal end that terminates within the interior volume of the balloon (Figure 1A, outer tube [8] and balloon [22]) with the distal end being in sliding engagement with the stiffening member so as to align the stiffening member with the axis of the shaft and to prevent transverse movement of the stiffening member in a direction generally perpendicular to the axis of the shaft (column 7, lines 55-57). Support for preventing transverse movement can be found above in paragraph 6, claim 1, section f.

In regards to claim 22, Sakai et al teaches that the stiffening member comprises a lumen configured to accommodate the passage of a wire guide (Figure 1A, second lumen [14]; column 7, lines 43-44; column 8, lines 20-22).

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al and Goodin, as applied to claim 9 above, and further in view of Hamilton et al (US 6,514,228).

In regards to claim 11, Sakai et al teaches that the distal end portion of the catheter comprises a distal end that terminates within the interior volume of the balloon (Figure 1A, outer tube [8] and balloon [22]), and that the distal end is joined to the proximal end of the balloon, but Sakai et al and Goodin do not teach the distal end is fixedly connected to the stiffening member. Hamilton et al teaches that a transition tube sealingly connects the distal end of the catheter to the proximal end of the balloon (column 5, lines 55-57). It would have been obvious to apply the teachings of Hamilton et al to the modified device of Sakai et al by providing a transition tube (i.e. indirectly fixing the distal end of the catheter to the stiffening member) between the distal end of the catheter and the stiffening member as the transition tube provides a fluid connection between the distal end of the catheter and the stiffening member (column 5, lines 52-55).

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al and Goodin, as applied to claim 8 above, and further in view of Stivland et al (US 2002/0128596).

In regards to claim 21, Sakai et al does not teach that the stiffening member comprises a solid wire having a circular cross-section, but Stivland et al teaches of a stiff core wire (Page 2, paragraph [0017]) with what appears to be a circular cross-section in Figure 1 (Figure 1, core wire [40]). It would have been obvious to apply the solid stiffening member with a circular cross-section taught by Stivland et al in replacement of the stiffening member of Sakai et al in order to provide additional stiffness, or rigidity, to the catheter structure.

13. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al, as applied to claim 13 above, and further in view of Walker et al (US 5,364,354).

In regards to claim 15, though Sakai et al does not teach of a sleeve comprising a cannula with the cannula having an interior cross-sectional area less than the interior cross-sectional area of the sleeve, Walker et al teaches of a collar disposed within the sleeve that has an interior cross-sectional area that is less than the interior cross-sectional area of the sleeve (figure 2, collar [52] and sleeve [50]) that is in slidable engagement with the sleeve since it is coupled to the guide wire which is also in slidable engagement with the sleeve (column 6, lines 20-21 and 37-39). To a person having ordinary skill in the art, a collar is synonymous to a cannula. To a person having ordinary skill in the art, in this case, the guide wire is performing the same function as the stiffening member. It would be obvious to apply the teachings of Walker et al to those of Sakai et al so that the slidable engagement of the cannula with the sleeve will also allow for slidable engagement of the stiffening member with the sleeve.

In regards to claims 16 and 17, though Sakai et al does not teach of the distal end of the stiffening member comprising a retaining portion made of a rounded bead so as to prevent the distal end of the stiffening member from passing through the cannula, Walker et al teaches of round retaining beads that have been soldered or brazed to the distal end of the guide wire (Figure 3, retaining beads [54] and [56]), and these retaining beads have an exterior cross-sectional area that is greater than the interior cross-sectional area of the collar (column 6, lines 63-65). To a person having ordinary skill in the art, a collar is synonymous to a cannula. As stated in the above paragraphs, to a person having ordinary skill in the art, in this case, the guide

wire is performing the same function as the stiffening member. It would be obvious to apply the retaining portion of Walker et al to the stiffening member of Sakai et al in order to retain the seal between the collar and sleeve so that the stiffening member can extend to a degree (column 6, lines 53-62).

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al and Walker et al (US 5,364,354), as applied to claim 13 above, and further in view of Ryan et al (US 5,108,416).

In regards to claim 18, though Sakai et al and Walker et al do not teach of the distal end of the balloon comprising an end cap with the sleeve being defined by the interior volume of the end cap, Ryan et al teaches that an end cap at the distal end of the balloon surrounds a sleeve (column 6, lines 26-28; figure 7A, end cap [28] and mounting sleeve [38]). It would be obvious to apply the end cap of Ryan et al to the distal end of the modified balloon of Sakai et al because Ryan et al teaches that the end cap will prevent the sleeve from detaching from the catheter shaft if compression forces are applied at the distal end of the balloon (column 6, lines 19-21).

15. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al and Goodin, as applied to claim 8 above, and further in view of Swanson (US 5,605,543).

In regards to claims 23 and 24, though Sakai et al and Goodin do not teach about varying stiffness properties of the stiffening member, Swanson teaches that the stiffening member has a first physical property at a first location and a second physical property at a second location with the first physical property being different than the second physical property. In more detail,

Swanson also teaches that the first physical property comprises a first stiffness and the second physical property comprises a second stiffness with the first stiffness being greater than the second stiffness and the first location being proximal to the second location. Swanson describes a guidewire tube composed of a proximal guidewire tube and a distal guidewire tube, with the proximal guidewire tube being stiffer than the distal guidewire tube (column 4, lines 43-52). It would have been obvious to apply the varying stiffness properties of the stiffening member taught by Swanson to those of the stiffening members of Sakai et al and Goodin to enhance pushability of the resultant catheter since the proximal end is stiffer than the distal end (column 4, lines 53-55).

16. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al, Goodin, and Swanson, as applied to claim 23 above, and further in view of Devens et al (US 7,163,523).

In regards to claim 25, though Sakai et al, Goodin, and Swanson do not teach of the stiffening member having a tapered cross-section, Devens et al teaches that the stiffening member has a tapered cross-section, since the outer diameter of the proximal section tapers to the smaller outer diameter of the distal section (column 7, lines 18-33). A study was conducted and the stiffening member with the tapered stiffening member had greater enhanced pushability compared to that of stiffening members with uniform cross-sections (column 9, lines 32-39; Table 1, Sample 8). It would have been obvious to apply the tapered cross-section element of the stiffening member taught by Devens et al to the stiffening members of Sakai et al, Goodin, and

Swanson in order to enhance pushability of the resultant catheter (column 9, lines 32-39; Table 1, Sample 8).

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shefali D. Patel whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDP
09/04/2007

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